EMERGENCY PROTOCOLS FOR TREATMENT OF ANAPHYLAXIS

Anaphylaxis is an acute systemic reaction that occurs upon administration of an antigen to which the individual has been previously sensitized. Symptoms usually commence within minutes after injection and may begin with local or generalized itching or burning, flushing, sweating, apprehension, irritative cough, pallor, nausea and vomiting. Occasionally there is rapid progression of signs and symptoms primarily involving the respiratory system (laryngeal edema, chest tightness, wheezing, dyspnea, cyanosis, voice changes related to laryngeal edema) and the cardiovascular system (profound shock, rapid and weak pulse, arrhythmia, unconsciousness, collapse). Cardiac arrest and death may follow due to hypoxia.

While the above symptoms represent the most extreme case, it must be kept in mind that MINOR REACTIONS occur more frequently and include flushing, hives, wheals, urticaria (often restricted to the injected extremity), and angioedema. If any of these symptoms appear during the immediate post-injection period, treatment should be started to prevent the development of more serious consequences.

The instructions on the following page are recommended only when a physician is not present to administer his/her own course of treatment. IT IS RECOMMENDED THAT THREE AMPULES OR PRELOADED SYRINGES OF 1 ML. OF 1:1000 EPINEPHRINE BE READILY AVAILABLE FOR USE DURING CLINIC HOURS. Epinephrine should protected from exposure to light.

The probability that such a reaction will occur is remote. Nevertheless, it is best to be alert and prepared for such emergencies. The outlined preliminary steps may prevent or hinder the progressive reaction to the point where the patient can be transferred to a nearby hospital for more definitive care.

Foremost, do all you can to prevent anaphylaxis by: 1) carefully eliciting history of prior reactions, 2) avoid giving injections to persons with known prior reactions and specific allergies, and 3) DO NOT ADMINISTER VACCINES TO PERSONS WITH KNOWN ALLERGIES TO THOSE SPECIFIC VACCINE COMPONENTS.

INSTRUCTIONS FOR TREATMENT OF ACUTE ANAPHYLAXIS AND/OR SEVERE ALLERGIC REACTIONS TO INJECTIONS (GIVEN IN THE COURSE OF NURSING DUTIES)

The following steps should be performed as necessary in the order given:

1. KEEP CALM AND START TREATMENT PROMPTLY. If you think the allergic reaction is progressing from the injection site to involve the whole extremity and perhaps the entire body, DO NOT WAIT FOR SYMPTOMS TO SUBSIDE. CALL FOR HELP.

2. For severe generalized reactions (shock, laryngeal edema, wheezing, urticaria, generalized pruritis):

- Administer 0.01 ml/kg aqueous epinephrine hydrochloride 1:1000 SUBCUTANEOUSLY into the limb opposite the injection site (1 kg=2.2 pounds). See chart below for dosage by weight.
- Massage area to promote absorption.
- Dosage may be repeated every 20-30 minutes as needed, based on frequent monitoring of blood pressure and pulse. Frequently, marked tachycardia and excitability make further administration of the drug unwise.

BODY WEIGHT	DOSAGE 1:1000 EPINEPHRINE
up to 15 lbs.	0.05 ml.
15 to 25 lbs.	0.10 ml.
26 to 40 lbs.	0.15 ml.
41 to 50 lbs.	0.20 ml.
51 to 60 lbs.	0.25 ml.
61 to 70 lbs.	0.30 ml.
71 to 80 lbs.	0.35 ml.
81 to 100 lbs.	0.40 ml.
above 100 lbs.	0.50 ml.

IF WEIGHT UNKNOWN	
Children 2-6 yrs.	0.15 ml.
Children 7-12 yrs.	0.20 ml.
12 yrs. to adult	0.50 ml.

SUPPLY LIST-EMERGENCY KITS FOR IMMUNIZATION CLINICS

Emergency kits must be available at each immunization site and will contain:

1. Three 1.0 ml preloaded syringes of aqueous epinephrine 1:1000

OR 2. Three 1.0 ml ampules of aqueous apinephrine 1:1000

3. Needles, syringes, alcohol swabs
4. Plastic oral airways
5. Gauze-wrapped tongue depressors
6. Benadryl 50 mg/ml
7. Ammonia perles
8. Stethoscope and blood pressure cuff
9. Tourniquets

3. If the reaction is severe, apply a tourniquet above the injection site to retard absorption. Do not cut off circulation to the limb. Check for pulse after applying tourniquet to make sure arterial flow has not been interrupted.

- IF THE ANTIGEN INJECTION WAS GIVEN SUBCUTANEOUSLY (NOT INTRAMUSCULARLY), inject an additional dose of epinephrine hydrochloride 1:1000 subcutaneously in a dose of 0.01 ml/lg (up to 0.3 ml) locally into the antigen injection site. This will slow absorption of the antigen.

4. MAINTAINING AN ADEQUATE AIRWAY IS ESSENTIAL. If at all possible and if the patient's condition warrants, he or she should be transferred immediately by ambulance to the nearest hospital emergency room.

- All nurses should be prepared to perform cardiopulmonary resuscitation if necessary, including external cardiac massage and mouth-to-mouth breathing. The primary concern should be to prepare the patient for transfer to a medical facility.
- Tracheotomy may be required in cases of severe laryngeal edema. Endotrachael intubation and assisted ventilation may be necessary in severe, unrelenting bronchospasm.

5. Lay the patient flat, with feet elevated, and keep warm with a blanket. If respiratory difficulty occurs, head and chest may be elevated slightly. Oxygen may be administered by mask or nasal catheter.

6. If the reaction is life-threatening (shock, laryngeal edema, wheezing), after above treatment has been completed, it may be necessary to administer medications intravenously. DO NOT BEGIN AN INTRAVENOUS INFUSION OR IV MEDICATIONS UNLESS INSTRUCTED BY A PHYSICIAN.

7. Inject Benadryl intramuscularly to inhibit the effects of further histamine release. Benadryl is NOT the primary drug to use in a severe or life-threatening reaction, but it may shorten the duration of the reaction and prevent relapses.

BODY WEIGHT	DOSAGE BENADRYL
15 lbs. Or less	0.125 ml. (6.25 mg.)
16 to 30 lbs.	0.25 ml. (12.5 mg.)
31 to 110 lbs.	0.5 ml. (25 mg.)
above 110 lbs.	1.0 ml (50 mg.)

8. Carefully monitor and record the patient's condition, including blood pressure, pulse, and respirations.

QUALIFICATIONS AND AIDS TO INTERPRETATION

(1) Anaphylaxis and anaphylactic shock mean an acute, severe, and potentially lethal systemic allergic reaction. Most cases resolve without sequelae. Signs and symptoms begin minutes to a few hours after exposure. Death, if it occurs, usually results from airway obstruction caused by laryngeal edema or bronchospasm and may be associated with cardiovascular collapse. Other significant clinical signs and symptoms may include the following: Cyanosis, hypotension, bradycardia, tachycardia, arrhythmia, edema of the pharynx and/or trachea and/or larynx with stridor and dyspnea. Autopsy findings may include acute emphysema which results from lower respiratory tract obstruction, edema of the hypopharynx, epiglottis, larynx, or trachea and minimal findings of eosinophilia in the liver, spleen and lungs. When death occurs within minutes of exposure and without signs of respiratory distress, there may not be significant pathologic findings.

(2) Encephalopathy. For purposes of the Vaccine Injury Table, a vaccine recipient shall be considered to have suffered an encephalopathy only if such recipient manifests, within the applicable period, an injury meeting the description below of an acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination.

(i) An acute encephalopathy is one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred).

(A) For children less than 18 months of age who present without an associated seizure event, an acute encephalopathy is indicated by a "significantly decreased level of consciousness" (see "D" below) lasting for at least 24 hours. Those children less than 18 months of age who present following a seizure shall be viewed as having an acute encephalopathy if their significant decreased level of consciousness persists beyond 24 hours and cannot be attributed to a postictal state (seizure) or medication.

(B) For adults and children 18 months of age or older, an acute encephalopathy is one that persists for at least 24 hours and is characterized by at least two of the following:

(1) A significant change in mental status that is not medication related; specifically a confusional state, or a delirium, or a psychosis;
(2) A significantly decreased level of consciousness, which is independent of a seizure and cannot be attributed to the effects of medication; and
(3) A seizure associated with loss of consciousness.

(C) Increased intracranial pressure may be a clinical feature of acute encephalopathy in any age group.

(D) A "significantly decreased level of consciousness" is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater (see paragraphs (2)(I)(A) and (2)(I)(B) of this section for applicable time frames):

(1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);

(2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or
(3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

(E) The following clinical features alone, or in combination, do not demonstrate an acute encephalopathy or significant change in either mental status or level of consciousness as described above: Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle. Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy. In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy.

(ii) Chronic encephalopathy occurs when a change in mental or neurologic status, first manifested during the applicable time period of at least 6 months from the date of vaccination. Individuals who return to a normal neurologic state after the acute encephalopathy shall not be presumed to have suffered residual neurologic damage from that event; any subsequent chronic encephalopathy shall not be presumed to be a sequela of the acute encephalopathy. If a preponderance of the evidence indicates that a child's chronic encephalopathy is secondary to genetic, prenatal or perinatal factors, that chronic encephalopathy shall not be considered to be a condition set forth in the Table.

(iii) An encephalopathy shall not be considered to be a condition set forth in the Table if in a proceeding on a petition, it is shown by a preponderance of the evidence that the encephalopathy was caused by an infection, a toxin, a metabolic disturbance, a structural lesion, agenetic disorder or trauma (without regard to whether the cause of the infection, toxin, trauma, metabolic disturbance, structural lesion or genetic disorder is known). If at the time a decision is made on a petition filed under section 2111(b) of the Act for a vaccine-related injury or death, it is not possible to determine the cause by a preponderance of the evidence of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the Table.

(iv) In determining whether or not an encephalopathy is a condition set forth in the Table, the Court shall consider the entire medical record.

(3) Residual Seizure Disorder. A petitioner may be considered to have suffered a residual seizure disorder for purposes of the Vaccine Injury Table, if the first seizure or convulsion occurred 5-15 days (not less than 5 days and not more than 15 days) after administration of the vaccine and 2 or more additional distinct seizure or convulsion episodes occurred within 1 year after the administration of the vaccine which were unaccompanied by fever (defined as a rectal temperature equal to or greater than 101.0 degrees Fahrenheit or an oral temperature equal or greater than 100.0 degrees Fahrenheit). A distinct seizure or convulsion episode is ordinarily defined as including all seizure or convulsive activity occurring within a 24-hour period, unless competent and qualified expert neurological testimony is presented to the contrary in a particular case.

For purposes of the Vaccine Injury Table, a petitioner shall not be considered to have suffered a

residual seizure disorder, if the petitioner suffered a seizure or convulsion unaccompanied by fever (as defined above) before the fifth day after the administration of the vaccine involved.

(4) Seizure and convulsion. For purposes of paragraphs (2) and (3) of this section, the terms, "seizure" and "convulsion" include myoclonic, generalized tonic-clonic (grand mal), and simple and complex partial seizures. Absence (petit mal) seizures shall not be considered to be a condition set forth in the Table. Jerking movements or staring episodes alone are not necessarily an indication of seizure activity.

(5) Sequela. The term "sequela" means a condition or event which was actually caused by a condition listed in the Vaccine Injury Table.

(6) Chronic Arthritis. For purposes of the Vaccine Injury Table, chronic arthritis may be found in a person with no history in the 3 years prior to vaccination of arthropathy (joint disease) on the basis of:

A) Medical documentation, recorded within 30 days after the onset, of objective signs of acute arthritis (joint swelling) that occurred between 7 and 42 days after a rubella vaccination;

B) Medical documentation (recorded within 3 years after the onset of acute arthritis) of the persistence of objective signs of intermittent or continuous arthritis for more than 6 months following vaccination;

C) Medical documentation of an antibody response to the rubella virus.

For purposes of the Vaccine Injury Table, the following shall not be considered as chronic arthritis: Musculoskeletal disorders such as diffuse connective tissue diseases (including but not limited to rheumatoid arthritis, juvenile rheumatoid arthritis, systemic lupus erythematosus, systemic sclerosis, mixed connective tissue disease, polymyositis/dermatomyositis, fibromyalgia, necrotizing vasculitis and vasculopathies and Sjogren's Syndrome), degenerative joint disease, infectious agents other than rubella (whether by direct invasion or as an immune reaction), metabolic and endocrine diseases, trauma, neoplasms, neuropathic disorders, bone and cartilage disorders and arthritis associated with ankylosis spondylitis, psoriasis, inflammatory bowel disease, Reiter's syndrome, or blood disorder.

Arthralgia (joint pain) or stiffness without joint swelling shall not be viewed as chronic arthritis for purposes of the Vaccine Injury Table.

(7) Brachial neuritis is defined as dysfunction limited to the upper extremity nerve plexus (i.e., its trunks, divisions, or cords) without involvement of other peripheral (e.g., nerve roots or a single peripheral nerve) or central (e.g., spinal cord) nervous system structures. A deep steady, often severe aching pain in the shoulder and upper arm usually heralds onset of the condition. The pain is followed in days or weeks by weakness and atrophy in upper extremity muscle groups. Sensory loss may accompany the motor deficits, but is generally a less notable clinical feature. The neuritis, or plexopathy, may be present on the same side as or the opposite side of the injection; it is sometimes bilateral, affecting both upper extremities. Weakness is required before the diagnosis can be made. Motor, sensory, and reflex findings on physical examination and the results of nerve

conduction and electromyographic studies must be consistent in confirming the dysfunction is attributable to the brachial plexus. The condition should thereby be distinguishable from conditions that may give rise to dysfunction of nerve roots (i.e., radiculopathies) and peripheral nerves (i.e., including multiple mononeuropathies), as well as other peripheral and central nervous system structures (e.g., cranial neuropathies and myelopathies).

(8) Thrombocytopenic purpura is defined by a serum platelet count less than 50,000/mm3. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with other causes such as hypersplenism, autoimmune disorders (including alloantibodies from previous transfusions) myelodysplasias, lymphoproliferative disorders, congenital thrombocytopenia or hemolytic uremic syndrome. This does not include cases of immune (formerly called idiopathic) thrombocytopenic purpura (ITP) that are mediated, for example, by viral or fungal infections, toxins or drugs. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with disseminated intravascular coagulation, as observed with bacterial and viral infections. Viral infections include, for example, those infections secondary to Epstein Barr virus, cytomegalovirus, hepatitis A and B, rhinovirus, human immunodeficiency virus (HIV), adenovirus, and dengue virus. An antecedent viral infection may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing. Bone marrow examination, if performed, must reveal a normal or an increased number of megakaryocytes in an otherwise normal marrow.

(9) Vaccine-strain measles viral infection is defined as a disease caused by the vaccine-strain that should be determined by vaccine-specific monoclonal antibody or polymerase chain reaction tests.

(10) Vaccine-strain polio viral infection is defined as a disease caused by poliovirus that is isolated from the affected tissue and should be determined to be the vaccine-strain by oligonucleotide or polymerase chain reaction. Isolation of poliovirus from the stool is not sufficient to establish a tissue specific infection or disease caused by vaccine-strain poliovirus.

(11) Early-onset Hib disease is defined as invasive bacterial illness associated with the presence of Hib organism on culture of normally sterile body fluids or tissue, or clinical findings consistent with the diagnosis of epiglottitis. Hib pneumonia qualifies as invasive Hib disease when radiographic finding consistent with the diagnosis of pneumonitis are accompanied by a blood culture positive for the Hib organism. Otitis media, in the absence of the above findings, does not qualify as invasive bacterial disease. A child is considered to have suffered this injury only if the vaccine was the first Hib immunization received by the child.